User Manual

PRIMO THERASONIC 360/460
Model 121/120

CE
0120

Contents

	page
Contents	3
General information	4
Record of amendments	4
Declaration of conformity to 93/42/EEC	5
Warranty	6
Introduction and indications for use	7
Contraindications	8
Accessories	9
Controls and markings	10
Installation	14
Operating Instructions	15
Protocols	22
Dose algorithm	23
Maintenance	24
Appendix A – Overview of treatment modality	25
Appendix B – Technical specification	27
Appendix C - EMC Tables	30
Appendix D – Essential performance	34

General information

This manual provides the necessary information for the installation and operation of the Primo Therasonic 360 and 460 Units.

These instructions must be studied before putting the unit into operation.

The information contained in this manual is subject to change without notice.

No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent of EMS Physio Ltd.

The Therasonic 360 is a single frequency and the 460 a dual frequency ultrasound therapy unit. The units may be mains only or mains/battery powered.

Therapeutic ultrasound has been applied to a wide range of conditions with successful outcomes. These include acute and sub acute traumatic and inflammatory conditions, chronic rheumatoid and arthritic conditions, scar and excessive fibrous tissue and for pain relief.

Record of amendments

ISSUE	COMMENTS	DATE
1	Initial Issue	4/06/2009
2	Revised	20/09/2010
3	Updated for models 120A/121A	08/04/2011
4	Revised declaration of conformity	16/03/2012
5	Ref to 21 CFR1050.10 added p.10	25/05/2012
6	Updated to show latest images	17/09/2012
7	Declaration of conformity revised	26/06/2014

EC Declaration of Conformity

Product Name	Primo Therasonic 460, 3601 & 3603
Model Numbers	120, 120A & 121, 121A

EMS Physio Ltd
Grove Technology Park, Downsview Road
Wantage, Oxfordshire, OX12 9FE, United Kingdom

Declares that the device listed above is in conformity with the essential requirements and provisions of the following EC Council Directives:

Directive	Conformity assessment route
2011/65/EU	Annex II, module A (768/2008/EC) (RoHS)
93/42/EEC	Annex II of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd. Class IIb according to Annex IX of 93/42/EEC

Signature	M Bowles
Position	Operations Director
Date	26th June 2014
Date first issued	4th June 2009

Warranty

This EMS Physio Ltd., (hereinafter called the Company) product is warranted against defects in materials and workmanship for a period of two years from the date of shipment. The Company will at its option, repair or replace components which prove to be defective during the warranty period, provided that the repairs or replacements are carried out by the Company or its approved agents.

The Company will consider itself responsible for the effects on safety, reliability and performance of the product: only if -

assembly operations, re-adjustments, modifications or repairs are carried out by persons authorised by it,

the product is used in accordance with the instructions for use,

the electrical installation of the relevant room complies with the appropriate national requirements.

Should the product be returned to the Company for repair it must be sent carriage paid.

Consumable items, for example, electrodes, electrode covers and batteries, are excluded from the above warranty.

It is intended that the Therasonic 360 and 460 units are only used by qualified healthcare professionals such as physiotherapists who have received training in electrotherapy.

Introduction

The Primo Therasonic 3601 provides 1MHz ultrasound therapy, the 3603 provides 3MHz ultrasound therapy, and the 460 provides both 1MHz and 3MHz ultrasound therapy.

Indications for use

Therapeutic ultrasound may be applied to a wide range of conditions with successful outcomes. These include acute and subacute traumatic and inflammatory conditions, chronic rheumatoid and arthritic conditions, scar and excessive fibrous tissue and for pain relief.

Ultrasound may also be used for phonophoresis – the movement of drugs through the skin under the influence of ultrasound. Some drugs are absorbed through the skin very slowly and ultrasound may be used to accelerate the process.

Contraindications

Tumours, as ultrasound affects tissue repair and could therefore encourage growth.

Infections, due to the risk of spreading the infection.

Pregnancy, treatment over the pregnant uterus as ultrasound could affect rapidly dividing cells.

Radiotherapy, sites that have received radiotherapy treatment during the last six months.

Thrombosis and impaired circulation.

Areas of impaired sensation.

Haemorrhage, due to the risk of increased bleeding, including recently controlled bleeding and haematoma.

Haemophilia.

Implanted devices such as cardiac pacemakers should be avoided due to the possibility of affecting their operation. Also some plastics used in replacement surgery may be affected by absorption of ultrasound energy. Metal implants may lead to reflections, and as a precaution low doses of ultrasound should be used near these.

Extreme care should be taken when treating areas near the eye because of the danger of damage to the retina.

Similarly, extreme care should be taken near the ears and reproductive organs.

Accessories supplied as standard

Catalogue Number	Description
SLA9000	DC power supply 18V 60W
PMA9125	Large dual-frequency transducer
EMS 502C	EMS coupling medium 250ml bottle

Optional accessories

PMA9126	Large single-frequency (1MHz) transducer
PMA9135	Small dual-frequency transducer
SLA9160	Combination therapy lead
EMS502	EMS coupling medium (8 x 250ml bottles)
EMS502A	EMS coupling medium 1litre bottle
EMS530	Primo shoulder bag
EMS158	Primo trolley

Supplied with each unit is a detachable mains lead suitable for the country to which it is delivered. Replacement or additional mains leads are shown below.

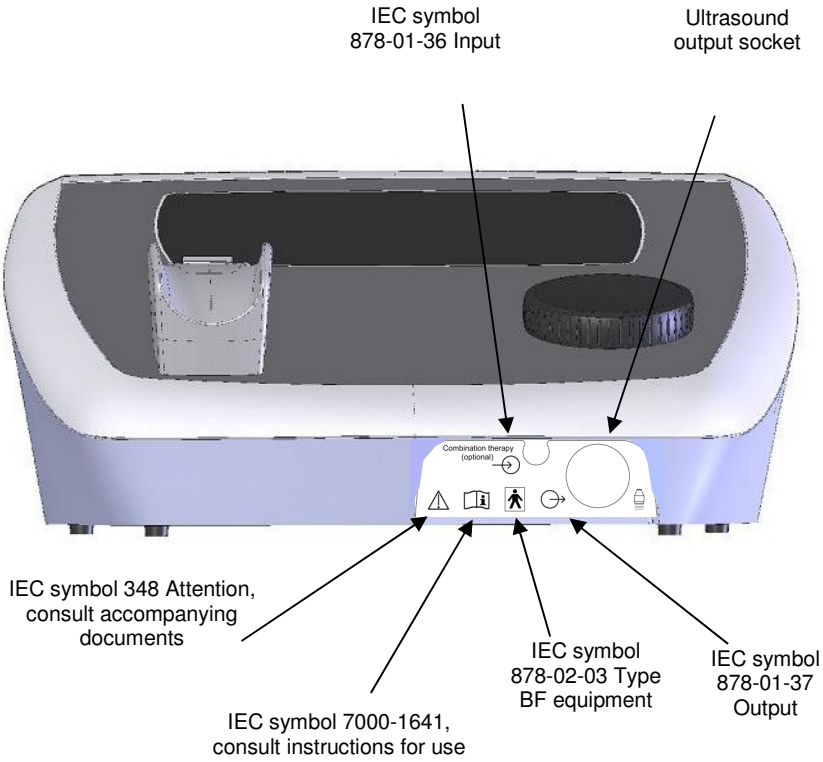
EMS Part Number	Description
6-85	UK mains lead
6-112	European mains lead
6-119	North America mains lead

For other countries contact EMS Physio Ltd. or the agent from whom the unit was purchased.

EMS Physio Ltd.
Grove Technology Park
Downsview Road
Wantage
Oxfordshire OX12 9FE
England
T: 01235 772272
F: 01235 763518
E: sales@emsphysio.co.uk
Website: http://www.emsphysio.co.uk

Controls and markings

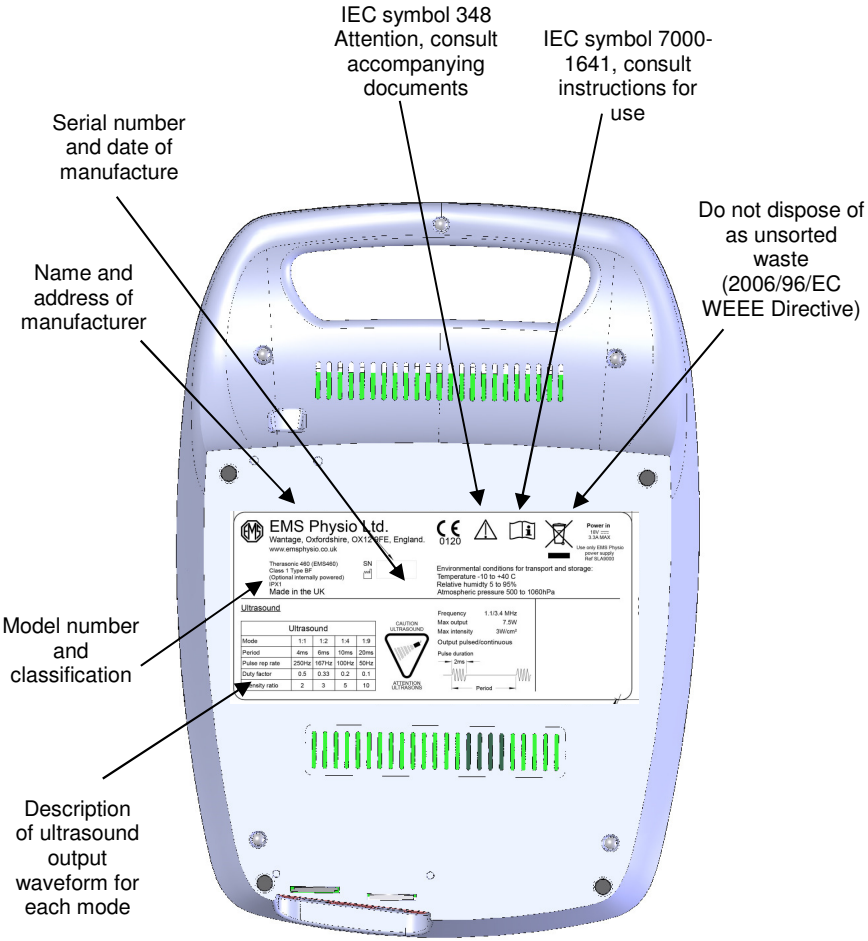
Therasonic 360 or 460 front panel



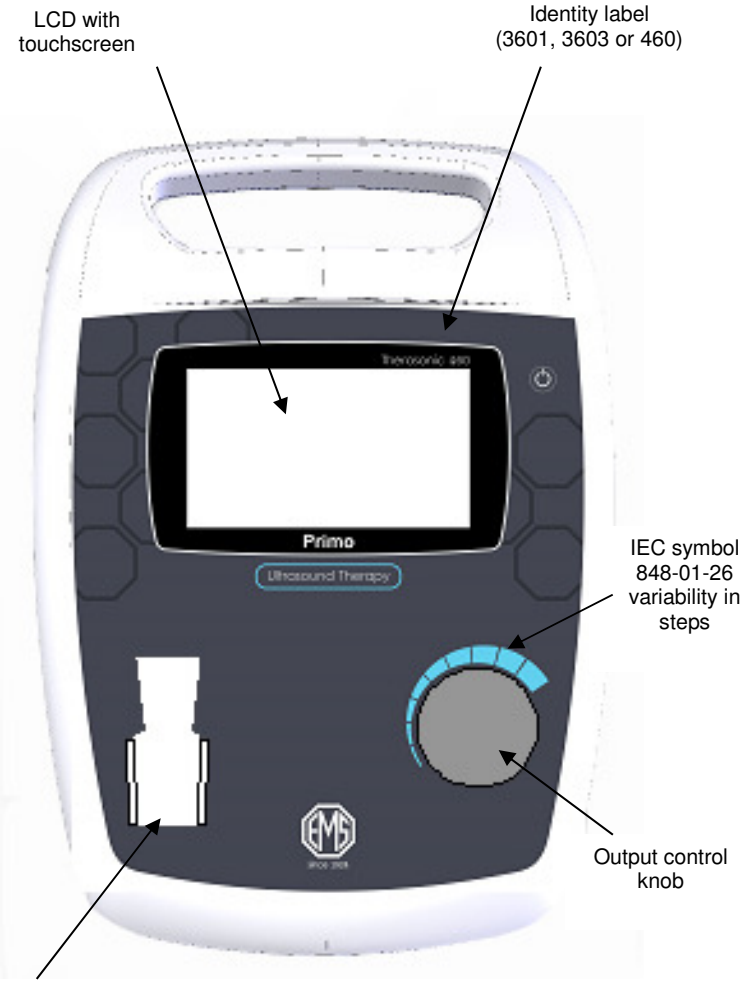
The **output socket** is for connection of the ultrasound transducer

The **stimulation input** is internally connected to the face of the ultrasound transducer and is intended for combination therapy. Any stimulator connected to the socket must be classified as type BF according to EN 60601-1 for continued safety. A suitable connecting lead is available from EMS Physio Ltd.

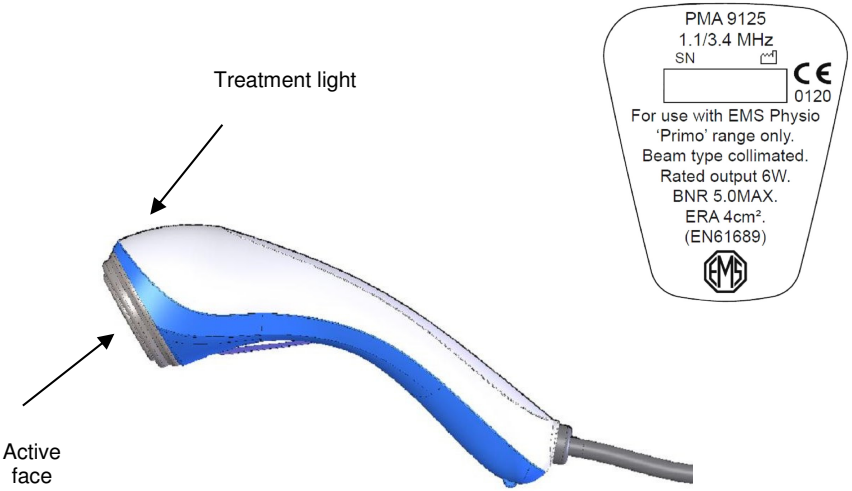
Therasonic 360 or 460 underside



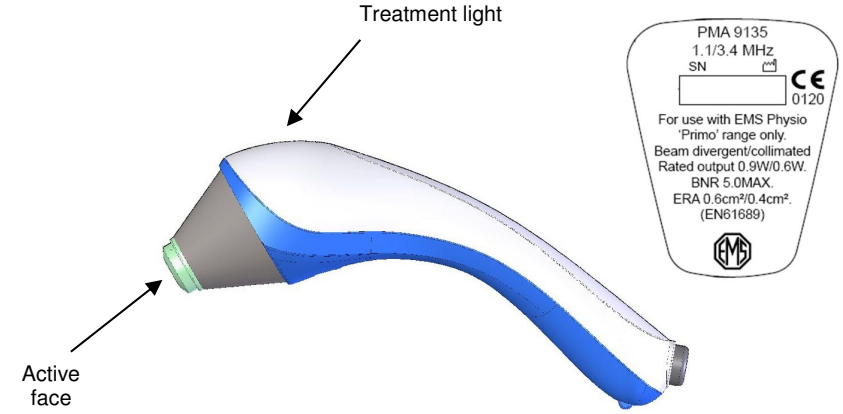
Therasonic 360 or 460 top



Large transducer



Small transducer



The ultrasound transducers are calibrated independently from the Primo Therasonic 460 and are fully interchangeable.

Installation

Upon receipt, check for any visible damage which may have occurred in transit. If any signs of damage are found then retain all packing material and inform the carrier and the Company or its agent from whom the unit was purchased.

The Therasonic 360 or 460 must only be used with an EMS Physio SLA9000 power supply (as supplied with the unit). Units fitted with an internal rechargeable battery may be used powered by the battery only.

The SLA9000 power supply must only be connected to a mains supply with a protective earth conductor. If the integrity of the earth connection is in doubt, do not connect it to the mains supply.

The Therasonic 360 or 460 unit is supplied with a large ultrasound transducer. An optional small transducer is available for the Therasonic 460.

Plug the ultrasound transducer into the output socket on the front right of the unit. The plug has an arrow and the word ‘top’ embossed on it to aid correct orientation.

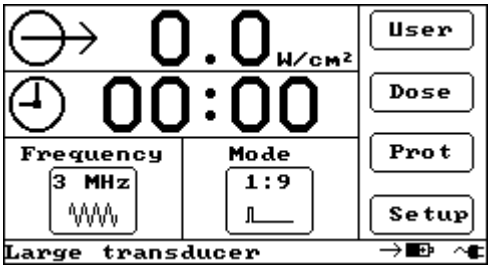
Operating instructions

Power on sequence and general information

Plug the output lead of the power supply into the socket on the rear of the unit and the mains plug to a suitable power outlet. The green power indicator on the power supply will light.

Switch on the unit by pressing and holding the on/off switch on the rear panel until the EMS logo is displayed on the LCD*.

After approximately 2 seconds the unit will give a short beep and the main ultrasound set-up screen will be displayed*.



At the bottom of the display is the status line. On the left is shown which transducer is connected to the output socket. On the right the symbol shows that the unit is connected to the mains supply.

*Start-up and Main screens will differ according to whether the unit is a Therasonic 360 or 460.
If the unit is fitted with a rechargeable battery, the battery symbol, , will be shown in the status line. The symbol is

shaded to show the current charge state of the battery. indicates a completely discharged battery and a fully charged battery. The arrow, →, to the left of the battery symbol will be shown if the battery is being charged. To conserve battery life, the unit will automatically turn off the LCD backlight after 1 minute and power itself down completely after 3 minutes if there has been no operator activity and the unit is running off the battery.

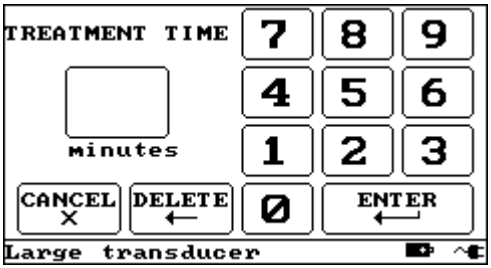
With the exception of the output intensity, all set-up and treatment parameters are set using the touch screen.

Ultrasound set-up

Treatment

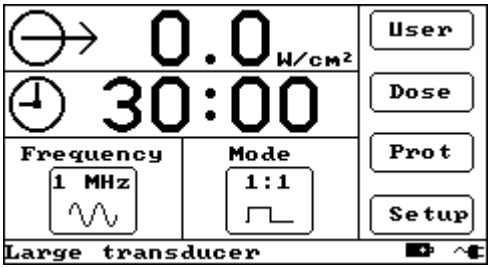
It is recommended that before commencing treatment, the stainless steel front of the transducer is disinfected using a 70% v/v aqueous solution of isopropyl alcohol. Sterile alcohol wipes are suitable for this purpose.

Touch the screen on the digits of the time display to increment the treatment time (maximum 30 minutes). Alternatively, touch the clock symbol to bring up the following screen:-



Type in the desired time and press ENTER to return to the main screen.

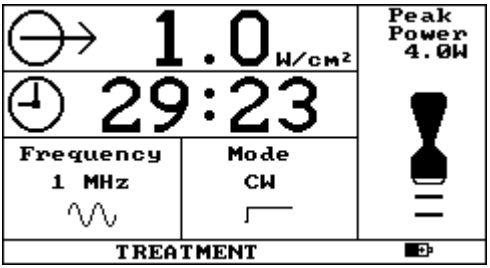
Select the desired ultrasound Frequency* and Mode (pulsed or continuous) by touching the relevant field on the screen.



Apply sufficient coupling medium to the area to be treated: EMS Therasonic coupling medium is recommended.

Apply the active face of the transducer to the treatment site via the coupling medium.

Turn the rotary control clockwise to start treatment. The output intensity will increase in 0.1 W/cm^2 steps. The treatment indicator on the transducer will light, the output symbol on the LCD will flash and the treatment time will begin to count down.



Move the transducer over the treatment site in small circular paths whilst setting the output intensity to the required level using the rotary control. If the transducer is not connected to the output socket or the treatment time is zero then the unit will give a two tone beep and the output will not be energised.

Always keep the face of the transducer in contact with the treatment area and always keep the transducer moving to avoid any standing waves.

If the transducer face is lifted from the treatment site or if for any reason there is insufficient contact between the transducer and the treatment site for more than two seconds, the power applied to the transducer will also be reduced to a low level. The treatment light on the transducer will turn off, the treatment time will cease to count down and the status bar will display CONTACT, indicating that the required output cannot be delivered. When good contact is restored, the treatment indicator on the transducer will light, the status bar will display TREATMENT and the timer will continue to count down.
If the output intensity is returned to zero using the rotary control, before the treatment time has elapsed, the display will show the treatment time remaining. When the intensity is increased again the treatment will continue.

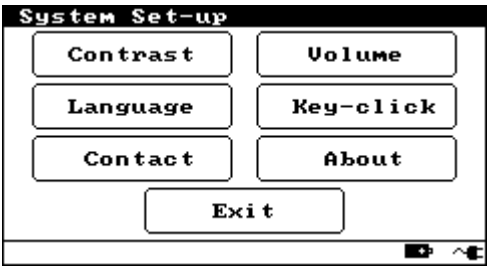
When the treatment time reaches 00:00, treatment is terminated. The intensity and power displays will go to zero, ultrasonic power from the transducer will be turned off, the treatment indicator will turn off and the unit will give a two second beep. Remove the transducer from the treatment site, wipe off any coupling medium and return the transducer to the holder at the rear of the unit.

Remove the remaining coupling medium from the treatment site.

The transducers are also suitable for treatment using a water bath. This is especially useful when treating areas which are not uniform such as feet or hands. When using a water bath it is advisable to use degassed water (water that has been boiled to remove any air and then allowed to cool). After the part of the body has been immersed in the water, remove any air bubbles that may have accumulated on the skin. Set up the treatment parameters and then immerse the transducer in the water before turning the output on. Hold the transducer with its face approximately 1 cm away from the treatment site and using the rotary control set the required intensity remembering to keep the transducer moving in small circular paths to prevent standing waves. At the end of the treatment the intensity and power displays will read zero, and the ultrasound power will turn off. Remove the transducer from the water and dry both it and the area treated.

System set-up menu

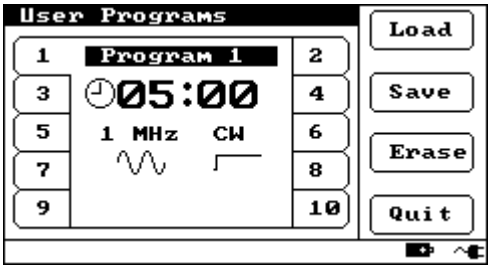
Touching the Setup button in the bottom right corner of the main screen takes you to the System set-up screen.



The Contrast button takes you to a screen where you can adjust the display contrast using up/down buttons, the Volume button allows for adjustment of the beeper volume (high or low), Language allows you to change the display language to any that may be installed in the unit and Key-click allows you to turn on or off the beep that happens whenever the screen is touched. Touching the Contact button gives you a screen with three options for the behaviour of the contact alarm – On is the default mode where poor contact turns out the contact light and stops the timer countdown – Off causes poor contact to turn out the contact light but not stop the timer countdown – Audio gives an additional beeping warning (light goes out, timer stops). The About button displays the model number and installed firmware version.

User programs

The Therasonic 360 or 460 can store up to 10 user defined set-ups. To access the user programs press the User button in the top right corner of the main screen.



The LCD shows the 10 user programs as file cards with numbered tabs. To select a program card just touch its tab.

To load a program press Load. The settings shown on the file card will be loaded and the user will be returned to the ultrasound set-up screen. If an empty card is selected the unit will give a short beep and no action will be taken.

To save the current ultrasound screen set-up as a user program, select the card to which the set-up is to be saved by touching its tab and press Save. The settings will be saved and displayed on the selected card.

To erase a program saved on the current card, press Erase. “Not Used” will be displayed on the selected card to confirm the action.

Select the Quit option to return to the main page.

****Differences between model 360 and 460 screens***

At start up, the screen will display the relevant model number. As the 360 is a single frequency unit (either 1 or 3 MHz) its Frequency button will be inactive and will display the set frequency of the unit. As the dose algorithm is not implemented on the 360 the Dose button is inactive. Protocols are not implemented in the 3603 so the Prot button will also be inactive.

Combination therapy

Any stimulator used with the Therasonic 360 or 460 for combination therapy must be Type BF (EN60601-1) for continued safety.

Attach a suitable electrode to the patient near the treatment site and connect it to one output from the 2-way cable from the stimulator. Connect one end of the combination therapy lead (SLA160) to the stimulator input on the front of the Therasonic 360 or 460 and the other to the remaining output on the 2-way cable of the stimulator.

It is recommended that only the large transducer is used for combination therapy in order to maintain sufficient contact area to keep the stimulator current density to a safe level.

Set up both the ultrasound and the stimulator ready for treatment. The stimulator treatment time should be set slightly longer than that for the ultrasound.

Apply coupling medium to the treatment site and position the ultrasound transducer on patient so that the lesion point is between the stimulator electrode and the ultrasound transducer.

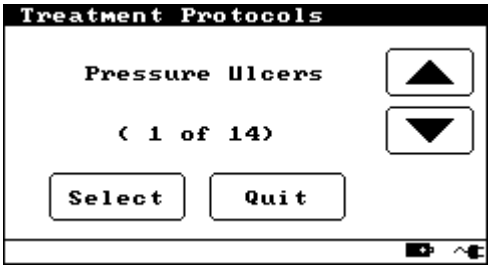
Turn on the stimulator output and slowly increase the intensity until the patient just feels the normal 'tingling' sensation associated with the modality.

Turn on the ultrasound output. The patient may feel a slight increase to the sensation. Increase the ultrasound intensity to the required level.

Move the ultrasound transducer towards the lesion area making sure that there is always coupling medium between the face of the transducer and the skin. When directly over the lesion, the patient will feel increased sensation - this is the centre of the lesion.

Treat with ultrasound and stimulation for the remaining time set.

Protocols (3601 & 460 only)

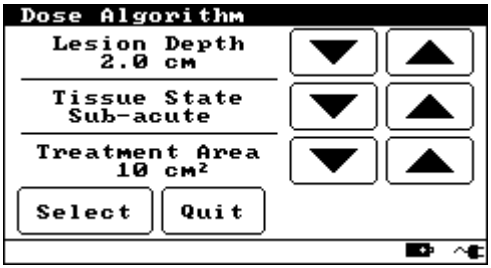


Pressing the Prot button will bring up the protocol selection screen. The various different treatment protocols can be selected by the Up/Down buttons. Pressing the select button will load the treatment settings for the selected protocol. Note that the maximum available intensity will be preset for each protocol to the recommended level for that treatment.

Before commencing treatment (by incrementing the output intensity) it is possible to edit the settings if required (the maximum available intensity will no longer be preset). It is also possible to store an edited version of a protocol as a user program, by pressing User and then selecting the program number and the Save option.

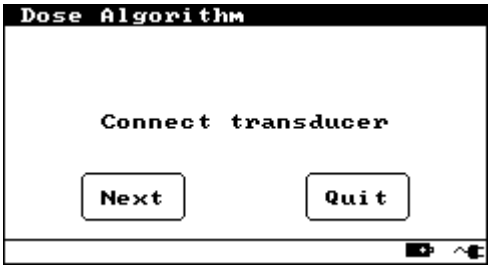
Dose algorithm (460 only)

Press the Dose button to produce this screen:-



The various parameters can be changed using the Up/Down buttons.

If an Ultrasound transducer is not connected this prompt screen will appear:-



Plugging in an ultrasound transducer at this point and pressing Next will cause a return to the Dose Algorithm display.

After adjusting the various parameters press the Select button and the algorithm will calculate and display the treatment settings for that particular set of input parameters. The maximum available intensity will also be automatically set to the value calculated by the dose algorithm.

Again, it is possible to edit and/or store these settings as described above in the protocols section. Increment the output intensity to begin treatment.

Maintenance

The ultrasound transducers may be disinfected using a 70% v/v aqueous solution of isopropyl alcohol. They are NOT suitable for steam sterilisation or for disinfectants containing sodium hypochlorite.

N.B. Isopropyl alcohol is flammable and should be kept away from naked flames. Isopropyl alcohol must not be brought into contact with eyes or mouth.

The unit may be cleaned by wiping over with a damp cloth (isopropyl alcohol wipes can be used to clean the touchscreen. The use of abrasive materials and cleaning solvents should be avoided.

Regularly (at least monthly) inspect all treatment leads, cables and connectors for signs of damage. The ultrasonic output power should be checked at least annually. Contact EMS Physio Ltd. service department for further information.

The Therasonic 360 and 460 have the option of an internal NiMh rechargeable battery pack (EMS161). Whenever the unit is connected to its power supply the battery is monitored and charged as necessary. This type of battery has a limited life (typically 500 charge / discharge cycles). This battery pack must only be replaced by authorised service personnel. Do not mutilate, puncture, or dispose of batteries in fire as the batteries can burst or explode, releasing hazardous chemicals. Discard used batteries according to the manufacturer's instructions and in accordance with your local regulations.

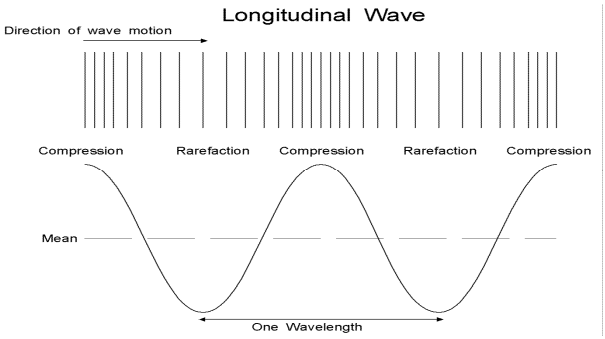
There are no user serviceable parts inside the unit and it should not be opened.

Full servicing instructions are available on request.

Appendix A – Overview of treatment modality

Sound is mechanical vibration. The human ear responds to these vibrations in the range 20 Hz to 20 kHz. Sound above 20 kHz is called ultrasound. Therapeutic ultrasound is sound in the range 500 kHz to 5 MHz.

Sound waves are produced by some disturbance in a material medium causing the particles or molecules of the medium to vibrate. For this reason sound will not pass through a vacuum. If the vibration is continuous and regular a constant tone or frequency is produced. The vibration or sound wave propagates through the medium as particles in the medium pass on their vibration to neighbouring particles and series of compressions and rarefactions are produced in the direction of travel of the wave. Therefore, sound waves are longitudinal waves.



The diagram shows a sound wave travelling from left to right. The vertical bars represent thin slices of the medium which are displaced to form areas of compression and rarefaction. The sinewave represents their displacement relative to their mean position. The distance over which the vibration repeats itself is called the wavelength. The number of complete vibrations in one second is called the frequency of the sound wave.
The velocity of sound in the medium is given by:

Velocity = frequency x wavelength

Sound will travel faster through media where the molecules are closer together and so the velocity is higher in solids than

in liquids, and higher in liquids than in gasses. For example, the velocity of sound in stainless steel is approximately 5800 m/s, in water 1500 m/s and in air only 330 m/s.

As the sound wave passes through the medium, causing molecules to vibrate, some of the energy in the wave is converted from kinetic energy to heat. For a collimated sonic beam the intensity, power per unit area, therefore, decreases exponentially with the distance travelled.

The attenuation of the beam is also dependent upon the frequency of the sound. In solids the attenuation is proportional to frequency, whereas in liquids the attenuation is proportional to the square of the frequency. The usual method of specifying the degree of attenuation of ultrasound in different media is by the half depth. The half depth is the distance the ultrasound must travel through the medium for its intensity to be reduced to one half of its original value. Many attempts have been made to measure the attenuation in various types of tissue with varying results. It is perhaps more important to remember which types of tissue have the highest absorption and which the lowest. With the lowest absorption first the order is, fat, muscle, skin, tendon, cartilage and bone. For soft tissue the half depth is around 50 mm at 1 MHz and 15 mm at 3 MHz.

It is also important to remember that where there is a change in medium or tissue type there will be both reflection and refraction of the ultrasound beam. In particular, there is almost 100% reflection at the interface of a solid or liquid to air at therapeutic ultrasound frequencies. Any air bubbles in coupling medium will therefore reduce the effective intensity of the ultrasound. Also bone reflects a high percentage of incident ultrasound. It is important, therefore, when applying ultrasound to keep the transducer orthogonal to the surface of the treatment area, to keep the ultrasound transducer moving and to use a good coupling medium to avoid unwanted reflections and locally high intensities.

Appendix B - Technical specification

General

Power input	18V, 3.33A external PSU
Battery (optional)	Internal rechargeable (NiMh)
Internal fuse	T3.15A
Classification (EN60601-1)	Class 1, Type BF
Size (h x w x d)	108 x 237 x 333 mm
Weight	1.3 kg (excluding battery)
Treatment programs	10 user-defined set-ups
Protocols (optional)	14 treatments
Dose algorithm (optional)	Calculates treatment settings from user entered parameters.

Ultrasound

Frequency	1.1 MHz ±5% and 3.4 MHz ±5%
Maximum intensity	1.5 W/cm^2 in CW 3.0 W/cm^2 in pulsed modes
Maximum output power	6 W average (mains operation only)
Output modes	CW and pulsed 1:1, 1:2, 1:4 and 1:9
Pulse duration	2 ms
Treatment timer	0 to 30 minutes (treatment linked)
Contact monitor	Light on transducer (audio option available).

Large ultrasound transducer

ERA	4 cm^2 (IEC 61689) 5 cm^2 (21 CFR 1050.10
BNR	<5
Beam type	Collimated

Small ultrasound transducer

	1MHz	3MHz
ERA	0.6 cm^2	0.4 cm^2
BNR	<5	<5
Beam type	Divergent	Collimated

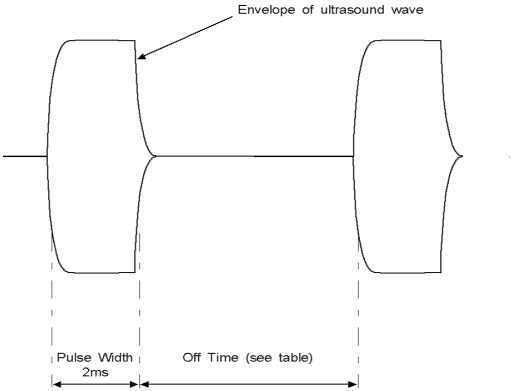
Transducers for use with the Therasonic 360 and 460 are fully interchangeable and suitable for underwater treatment (IPx7 rated).

The Therasonic 360 or 460 power supply is designed to operate from any 50/60 Hz single phase supply between 100 and 240 Vac capable of supplying 50 VA. Connection is via an IEC socket on the power supply.

The serial number and month/year of manufacture are located on the bottom of the unit.

Each Therasonic 360 or 460 is supplied with a power supply and detachable mains cable, a 4 cm^2 treatment head, 250ml bottle of Therasonic coupling medium and this manual.

The Therasonic 360 and 460 have been designed to meet the requirements of BS EN 60601-1:2006 “Medical Electrical Equipment, Part 1:General requirements for Safety”, BS EN 60601-2-5:2000 “Medical Electrical Equipment, Part 2.5 Particular requirements for the safety of ultrasonic physiotherapy equipment”



Pulse Mode	*Frequency*	*Off Time*	*Duty Cycle*	*Temporal peak to average ratio*
1:1	250 Hz	2 ms	50%	2:1
1:2	166 Hz	4 ms	33%	3:1
1:4	100 Hz	8 ms	20%	5:1
1:9	50 Hz	18 ms	10%	10:1

The pulse width is fixed at 2 ms

Environmental conditions for transport and storage

Temperature	-10 to +35 C
Relative humidity	5 to 95%
Atmospheric pressure	500 to 1060 hPa

Output display

The Therasonic 360 or 460 display shows the temporal-peak spatial-average ultrasound intensity and optionally the temporal-average power or the temporal-peak power as selected

Appendix C - EMC tables

1	**Guidance and manufacturers declaration – electromagnetic emissions**		
2	The Primo Therasonic 360 and 460 are intended for use in the electromagnetic environment specified below. The customer or the user of the 360 or 460 should assure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment - guidance**
4	RF emissions CISPR 11	Group 1	The 360 and 460 use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
6	RF emissions CISPR 11	Class A	The 360 and 460 are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
7	Harmonic emissions IEC 6100-3-2	not applicable	
8	Voltage fluctuations Flicker emissions IEC 61000-3-3	not applicable	

Guidance and manufacturers declaration – electromagnetic immunity			
The Primo Therasonic 360 and 460 are intended for use in the electromagnetic environment specified below. The customer or the user of the 360 or 460 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% *UT* (>95% dip in *UT*) For 0,5 cycle 40% *UT* (60% dip in *UT*) For 5 cycles 70% *UT* (30% dip in *UT*) For 25 cycles <5% *UT* (>95% dip in *UT*) For 5 sec	<5% *UT* (>95% dip in *UT*) For 0,5 cycle 40% *UT* (60% dip in *UT*) For 5 cycles 70% *UT* (30% dip in *UT*) For 25 cycles <5% *UT* (>95% dip in *UT*) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 360 and 460 requires continued operation during power mains interruptions, it is recommended that the 360 and 460 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *UT* is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturers declaration – Electromagnetic immunity.			
The Primo Therasonic 360 and 460 are intended for use in the electromagnetic environment specified below. The customer or user of the Primo Therasonic 360 or 460 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Solo Therasonic 360 or 460 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC61000-4-6	3Vrms 150kHz to 80MHz 3V/m	3V 3V/m	**Recommended separation distance** $d=3.5\sqrt{P}/V_1$
Radiated RF IEC61000-4-3	80MHz to 2.5GHz		$d=3.5\sqrt{P}/E_1$ 80MHz to 800MHz $d=7\sqrt{P}/E_1$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter according to the manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80MHz and 800MHz the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Primo Therasonic 360 or 460 is used exceeds the applicable RF compliance level above, the Primo Therasonic 360 or 460 should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as re-orienting or relocating the Primo Therasonic 360 or 460.

[b] Over the frequency range 10kHz to 80Mhz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Primo Therasonic 360 or 460

The Primo Therasonic 360 and 460 are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the 360 or 460 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Primo 360 or 460 as recommended below, according to the maximum output power of the communications equipment.

	150kHz to 80MHz $d=3.5\sqrt{P}/V_1$	**80MHz to 800MHz** $d=3.5\sqrt{P}/E_1$	**800MHz to 2.5GHz** $d=7\sqrt{P}/E_1$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix D - Essential performance

Power Input	100-240V ac
Ultrasound	
Frequency	1.1 MHz ±5% and 3.4 MHz ±5%
Maximum intensity	1.5 W/cm^2 (±20%) in CW 3.0 W/cm^2 (±20%) pulsed modes
Maximum output power	6 W (±20%) average
Output modes	CW and pulsed 1:1, 1:2, 1:4 and 1:9
Pulse duration	2 ms (±10%)
Treatment timer	0 to 30 minutes
Large transducer	ERA 4cm^2 (±20%) (IEC61689), collimated BNR<5
Small transducer	ERA 0.6cm^2 (±20%) (IEC61689), divergent at 1MHz ERA 0.4cm^2 (±20%) (IEC61689), collimated at 3MHz BNR<5

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